

REMARKS

Examiner Samantha L. Shterengarts, and Primary Examiner Kamal A. Saeed, are thanked for the courtesy of a telephonic interview with applicants' undersigned attorney, Barry I. Hollander on February 22, 2010, the substance of which is provided below with. During the interview, new claims 20-34, the restriction requirement, and the rejections were discussed with the Examiners, and further details on the substance of the interview are discussed below.

Claims 20-34 are pending in the application. By this amendment claims 1-19 have been cancelled without prejudice or disclaimer and new claims 20-34 have been added. Support for the new claims is provided, for example, by original claims 1, 2, 6, 7, 9, 10, and 15-19, and in the specification at pages 5-18. As discussed with the Examiners, support for W as representing a phenyl group is provided, for example, by page 6 where W may be a substitutable benzene ring. Also, as discussed support for R_{12} in the definition of Q as representing $-(CH_2)_mCOOR_{36}$ is provided, for example, by page 10 where R_{12} may be a substitutable alkyl group having 1 to 15 carbon atoms, and the substituents include a carboxyl group and alkoxycarbonyl group (page 17 lines 10-14), and thus $-COOR_{36}$ (R_{36} is H or C_{1-5} alkyl) in the definition of R_{12} is supported. As requested by the Examiners, the specification has been amended to provide clear antecedent basis in the specification for R_{12} representing $-(CH_2)_mCOOR_{36}$ wherein m represents an integer of 1 or 2 and R_{36} represents a hydrogen atom or an alkyl group

having 1 to 5 carbon atoms. This amendment to the specification is made in paragraph [0021], and is similarly supported for example, by page 10 where R_{12} may be a substitutable alkyl group having 1 to 15 carbon atoms, and the substituents include a carboxyl group and alkoxycarbonyl group (page 17 lines 10-14). Also, as discussed with the Examiners, support for the compounds of claims 24, and 32-34 is found, for example, in compound no. 51 at page 224, compound no. 84 at page 253, and compound no. 91 at page 260. The Examiners indicated that they believed that the new claims were supported by the specification. No new matter has been introduced.

Applicants gratefully acknowledge that the Examiner has indicated that the elected species (compound 91) is free of the prior art, and has continued the examination to include all products of formula 1. New claim 34 is directed to compound 91 and should be allowable.

Information Disclosure Statement

As discussed with the Examiners, a Supplemental Information Disclosure Statement was filed on January 28, 2010.

Priority Documents

As discussed with the Examiners, in the Office Action Summary, the claim of priority is acknowledged but the Summary indicates that only "some" of the certified

copies have been received. However, as discussed with the Examiners, the certified copies of the two Japanese priority documents should have been transmitted by the International Bureau, and the USPTO online database (PAIR) indicates that the certified copies of the two Japanese Priority documents (JP2004-068229, filed March 10, 2004, and JP2004-350599 filed December 3, 2004) are in the file. Accordingly, the Examiners indicated that they would acknowledge receipt of all certified copies of the priority documents.

The Examiner has required a certified translation of the priority document to grant the claim for priority with respect to overcoming the rejection of the claims under 35 U.S.C. 102(a) as being anticipated by Yamazaki et al (WO2004/02469, published 3/25/047). As discussed with the Examiners, the Office Action refers to “an interfering reference” and 37 CFR 41.154(b) and 41.202(e) which relate to the declaration of an interference. However, it was agreed by the Examiners during the interview that the Examiner meant to refer to an “intervening reference” as referred to in MPEP 201.15. Also, as pointed out to the Examiners, an interference would not be applicable with the Yamazaki et al reference because the cases are commonly assigned.

To obtain benefit of the Japanese priority application to overcome the rejection under 35 U.S.C. 102(a), a certified English translation of the priority document JP2004-068229, filed March 10, 2004, is being submitted as requested by the Examiner.

The Examiner is respectfully requested to make a determination of support and benefit of priority of the priority document.

Applicants note support for W as representing a phenyl group is provided, for example, in the English translation of the priority document in claim 1, page 2, and at page 27, where W may be a substitutable benzene ring. In addition, Applicants note support for R_{12} in the definition of Q as representing $(CH_2)_mCOOR_{36}$ is provided, for example, by claim 1 at page 5 last two lines, and page 31 where R_{12} may be a substitutable alkyl group having 1 to 15 carbon atoms, and the substituents may include a carboxyl group and alkoxycarbonyl group (page 37 line 5 from the bottom to page 38 line 12), and thus - $COOR_{36}$ (R_{36} is H or C_{1-5} alkyl) in the definition of R_{12} is supported.

The Restriction Requirement

In the Office Action, the Examiner has maintained the restriction requirement and has acted upon elected product claims 1-15. Elected product claims 1-15 have been cancelled and non-elected method claims 16-19 have been cancelled without prejudice or disclaimer. New claims 20-29, and 32-34 are product claims readable on elected Group I product claims. New claims 30-31 are method of use claims readable on non-elected method of use claims of Group II.

In the Office Action, the Examiner argues that the inventions lack a special technical feature which defines over the prior art because the compounds are taught by

the Yamazaki reference WO04/024697. However, as discussed with the Examiners during the interview, even if a special technical feature is lacking, there is unity of invention if, as here, the claims are for a product and a method of use of the product. See 37 C.F.R. 1.475(b)(2).

As stated in the restriction requirement, the Group II claims, claims 16-19, and new claims 31-32 are drawn to methods of using products of formula 1, which is one of the five combinations of categories permitted under 1.475(b), section 2 which provides:

(b) An international or a national stage application containing claims to different categories of invention **will be considered to have unity of invention** if the claims are drawn only to one of the following combinations of categories:

(1) A product and a process specially adapted for the manufacture of said product; or

(2) **A product and process of use of said product;** or... (Emphases Added.)

In addition, as discussed with the Examiners during the interview, the inventions do not lack a special technical feature which defines over the prior art because the Yamazaki reference WO04/024697 is not prior art for reasons as set forth below. During the interview, the Examiners indicated that upon a finding of allowability of the product claims, the method claims would be rejoined.

As indicated above, the Examiner has indicated that the elected species (compound 91) is free of the prior art, and has continued the examination to include all products of formula 1. Accordingly, a further election of species is not required.

In view of the foregoing, it is respectfully requested that the Examiner reconsider the requirement for restriction, and withdraw the same so as to give an examination on the merits on all of the claims pending in this application.

Rejection Under 35 U.S.C. 112, first paragraph - Enablement of PRODRUGS

All of the elected claims, claims 1-15 are rejected under 35 U.S.C. 112 first paragraph, on the grounds that the specification does not reasonably provide enablement for prodrugs of the compounds of Formula (1). However guidance as to prodrugs which may be used is given in the present specification at page 18 first full paragraph, and by specific compounds in Table 1 of the specification. The specific compounds give guidance to those skilled in the art for making prodrugs of those compounds as well as other prodrugs of compounds of formula (1) of claim 18. Comparing the structures of the compounds in Table 1 with the structures of their prodrugs provides guidance as to the location and types of substituents on the compounds of formula (1) and the prodrug groups which could replace them. Those skilled in the art would be guided, for example, to substitute one or more groups as disclosed on page 18, for another group of a specific prodrug compound. In any event, as discussed with the Examiners, to reduce the issues, the term "prodrug" has been deleted from the claims without prejudice or disclaimer.

Reconsideration and withdrawal of the rejection is respectfully requested.

Rejection Under 35 U.S.C. 112, first paragraph - Written Description - Generic Claim

All of the elected claims, claims 1-15, are rejected under 35 U.S.C. 112 first paragraph, as failing to comply with the written description requirement. The Office Action maintains that the compounds reduced to practice support the substituents listed on page 13 paragraph II of the Office Action. However, applicants do not have to provide working examples for every compound. As discussed with the Examiners, Table 1 presents structures for 122 specific compounds and Examples 1-5 presents pharmaceutical data for over 40 of those compounds (e.g. Table 2 presents EC50 data for 43 of those compounds). The specification demonstrates that the applicants had possession of the invention and the broad generic claims are adequately supported. In any event, claims 1-15 have been cancelled without prejudice or disclaimer, and new product claims have been presented directed to substituents as listed on page 13 paragraph II of the Office Action.

Reconsideration and withdrawal of the rejection is respectfully requested.

Rejection Under 35 U.S.C. 112, first paragraph – Enablement of Generic Claim

All of the elected claims, claims 1-15, are rejected under 35 U.S.C. 112 first paragraph, as failing to comply with the enablement requirement. The Office Action maintains that the specification does not enable any person skilled in the art to use the invention commensurate in scope with the claims because SAR studies are not available

for the claimed genus of compounds and it is not known what structural modifications are needed to make a compound active as anti-virals and antagonists against chemokine receptor CXCR4. However, as discussed above, applicant's do not have to provide working examples for every compound. As discussed with the Examiners during the interview, Table 1 presents structures for 122 specific compounds and Examples 1-5 presents pharmaceutical data for over 40 of those compounds (e.g. Table 2 presents EC50 data for 43 of those compounds). The specification provides guidance to those skilled in the art as to what structural modifications are needed to make a compound active as anti-virals and antagonists against chemokine receptor CXCR4. In any event, claims 1-15 have been cancelled without prejudice or disclaimer, and new product claims have been presented directed to substituents as listed on page 13 paragraph II of the Office Action.

Reconsideration and withdrawal of the rejection is respectfully requested.

Rejection Under 35 U.S.C. 112, second paragraph--Indefiniteness

Claims 1-10, and 15 are rejected under 35 U.S.C. 112 second paragraph, as being indefinite on the grounds that the claims recite various formula names for each formula described within the claim. The Examiner apparently requests deletion of either the bracketed [] formula numbers or the parenthetical () formula numbers. As discussed with the Examiners, although claims 1-10, and 15 have been cancelled without prejudice

or disclaimer, the bracketed [] numbers have been deleted in the new claim set, in accordance with the Examiner's request.

Reconsideration and withdrawal of the rejection is respectfully requested.

Rejection Under 35 U.S.C. 102(a)

All of the elected claims, claims 1-15, have been rejected under 35 U.S.C. 102(a) as being anticipated by commonly owned International Patent Application Publication No. WO04/024697 to Yamazaki et al, published March 25, 2004. This rejection is respectfully traversed.

The Office Action maintains that specific compounds disclosed in the Table of the Yamazaki reference anticipate the claims. The rejection may be overcome by perfecting the claim for priority as discussed above.

To obtain benefit of the Japanese priority application to overcome the rejection under 35 U.S.C. 102(a), a certified English translation of the priority document JP2004-068229, filed March 10, 2004, is being submitted as requested by the Examiner.

The Examiner is respectfully requested to make a determination of support and benefit of priority of the priority document.

As discussed above, Applicants note support for W as representing a phenyl group is provided, for example, in the English translation of the priority document in claim 1, page 2, and at page 27, where W may be a substitutable benzene ring. In addition,

applicants note support for R_{12} in the definition of Q as representing $(CH_2)_mCOOR_{36}$ is provided, for example, by claim 1 at page 5 last two lines, and page 31 where R_{12} may be a substitutable alkyl group having 1 to 15 carbon atoms, and the substituents include a carboxyl group and alkoxycarbonyl group (page 37 line 5 from the bottom to page 38 line 12), and thus - $COOR_{36}$ (R_{36} is H or C_{1-5} alkyl) in the definition of R_{12} is supported.

As discussed with the Examiners, for the specific compounds of claims 24, and 32-34, it is noted that:

A) 3-[(4-dipropylamino-butyl)-(4-[(1H-imidazol-2-ylmethyl)-(1-methyl-1H-imidazol-2-ylmethyl)-amino]-methyl)-benzyl)-amino]-propionic acid of claims 24 and 32 is compound no. 51 at page 224 and Table 1 of the present specification, and is also compound 51 in Table 1 at page 255 of the priority application JP2004-068229, filed March 10, 2004;

B) [[4-(dipropyl-amino)-butyl]-(4-[[1H-imidazol-2-ylmethyl)-(1-methyl-1H-imidazol-2-ylmethyl)-amino]-methyl]-benzyl)-amino]-acetic acid ethyl ester of claims 24 and 34, is compound no. 91 at page 260 of the present specification and the Examiner has indicated that the elected species (compound 91) is free of the prior art; and

C) [(4-dipropylamino-butyl)-(4-[(1H-imidazol-2-ylmethyl)-(1-methyl-1H-imidazol-2-ylmethyl)-amino]-methyl)-benzyl)-amino]-acetic acid of claims 24 and 33, is compound no. 84 at page 253 of the present specification.

It is noted that Compounds 84 and 91 are close in structure to compounds 34, 51, 54, 56-59, 72 and 73 of the Japanese priority application JP2004-068229 and are subgenerically covered by groups or substituents disclosed in JP2004-068229. Moreover, as discussed with the Examiners, the structures of compounds 84 and 91 are similar, and in the Office Action the Examiner has acknowledged that compound 91 is free of the prior art. Accordingly, claims 25 and 33-35, directed to compounds 51, 84, and 91 should each be allowable.

The Examiners did not commit to allowability of claims 24, and 32-34, indicating that the compounds had to be searched.

Reconsideration and withdrawal of the rejection is respectfully requested.

Double Patenting Rejections

Claims 1-4, 6-9, and 11-15 are rejected on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9 of commonly assigned U.S. Patent No. 7,176,227 (incorrectly cited as 7,716,227) to Yamazaki et al. The Office Action maintains that claims 1-9 of the reference fall completely within the broader present claims. However, as discussed with the Examiners during the interview, claims 1-15 have been cancelled without prejudice or disclaimer. As to the present new claim set, R_{12} represents $-(CH_2)_mCOOR_{36}$, wherein m represents an integer of 1 or 2 and R_{36} represents a hydrogen atom or an alkyl group having 1 to 5 carbon atoms. However,

in the claims of U.S. Patent No. 7,176,227, R_{12} represents a hydrogen atom or an alkyl group, and so as pointed out to the Examiners, the patent claims do not fall within the present claims.

Reconsideration and withdrawal of the rejection is respectfully requested.

Claims 1-4, 6-9, and 11-15 are rejected on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 18-32 and 49-65 of commonly assigned copending U.S. Patent Application No. 11/704,860. The Office Action maintains that claims 18-32 and 49-65 of the copending application fall completely within the broader present claims. However, as pointed out to the Examiners, claims 1-4, 6-9, and 11-15 have been cancelled without prejudice or disclaimer. As to the present new claim set, D is $-Q-Y-B$ where Q is NR_{12} , and R_{12} represents $-(CH_2)_mCOOR_{36}$, wherein m represents an integer of 1 or 2 and R_{36} represents a hydrogen atom or an alkyl group having 1 to 5 carbon atoms. However, in independent claims 18, 51, 54 (compound 23), 55, and 58 and their dependent claims of U.S. Patent No. Application No. 11/704,860, R_{12} represents a hydrogen atom or an alkyl group, and so as pointed out to the Examiners, those claims of copending U.S. Patent Application No. 11/704,860 do not fall within the present claims. Also, in the present new claim set, X is CH_2 , and W is a phenyl group or naphthyl group. However, unlike the present claims, for copending U.S. Patent Application No. 11/704,860: a) in independent claim 55, X is

SO₂, b) in independent claim 56 Q is O, c) in independent claim 57 W is not phenyl or naphthyl, and Q is a single bond, d) in independent claim 58 W is alkylene and Q is a single bond, and e) in independent claim 59, X is C=O, and D is not -Q-Y-B. For independent claim 54 which is compound 23 of the copending application, X is C=O and not CH₂ as in the present claim set. Accordingly, as pointed out to the Examiners, independent claims 51, 54, 55, 56, 57, 58, and 59 and their dependent claims of copending U.S. Patent Application No. 11/704,860 do not fall within the present claims.

Reconsideration and withdrawal of the rejection is respectfully requested.

CONCLUSION

For the reasons discussed above, it is respectfully submitted that this application is in condition for allowance and the rejections should be withdrawn. Favorable consideration with early allowance of the application is most earnestly requested.

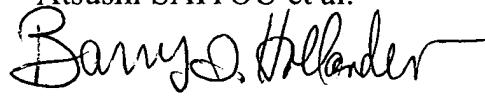
A request for a three month extension of time is being filed concurrently herewith.

As discussed during the telephonic interview, if the Examiner has any questions, or wishes to discuss this matter, please call the undersigned at the telephone number indicated below.

While it is believed that no fees are due with this amendment, the U.S. Patent and Trademark Office is hereby authorized to charge any fees which may be deemed

SAITOU et al. - Serial No. 10/591,722
Amendment Under 37 C.F.R. 1.111 And Record of Telephonic Interview
Attorney Docket: MOEG-P100

necessary to Deposit Account No. 19-0089 (MOEG-P100 P33287).

Respectfully submitted,
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Enc. certified English translation of priority document JP2004-068229, filed March 10,
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